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HE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Hideaki Imamura, et al.

Serial No. 10/565,327

Filed: January 20, 2006

For: CRYSTALLINE

6-N-PYRIDYLMETHYLAMINOINDOLOCARBAZOLE

COMPOUNDS

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450

Art Unit: To be determined

Examiner: To be determined

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

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- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

### INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

		RELATED AF	RELATED APPLICATION			
	U. S. SERIAL NUMBER	FILING DATE	MERCK CASE			
If thi	is is inconvenient, additional copies will be submitted upon requ	est.				
$\epsilon$	6. In accordance with 37 C.F.R. 1.97, (check one)					
	the attached information is filed within three months of the filing	date of the captioned case.				
	the attached information is filed more than three months after the Office Action on the merits.	e filing date but prior to the	mailing of a first			
	the attached information is filed before the mailing of a first Office examination under §1.114.	e action after the filing of a	request for continued			
	the attached information is being filed more than three months a Office Action on the merits, but before the mailing date of a Fina otherwise closes prosecution in the application. The enclosed a Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p	Action, Notice of Allowand uthorization is therefore given	e, or an action that			
	each item of information contained in this Information Disclosure from a foreign patent office in a counterpart foreign application n Statement.					
	each item of information contained in the information disclosure from a foreign patent office in a counterpart application and this designated in §1.56(c) more than thirty days prior to the filing of	communication was not red	ceived by any individual			
	no item of information contained in this Information Disclosure S foreign patent office in a counterpart foreign application, and, to after making reasonable inquiry, was known to any individual demonths prior to the filing of this Statement.	the knowledge of the perso	n signing the certification			
		Respectfully submitted,				
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ý		By: David A. Muthard  Attorney For Ap	nlicant(s)			
•		Reg. No. 35,297	phodric(5)			
		MERCK & CO., INC.				
		Patent Dept., RY60-30				
		P.O. Box 2000 Rahway, N.J. 07065-090	17			
		(732)594- <u>3903</u>	JI			

Date: August 1, 2006

Art Unit:

Examiner:

To be determined

To be determined



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Hideaki Imamura, et al.

Serial No.:

10/565,327

Case No.: BY0018YP

Filed:

January 20, 2006

For:

CRYSTALLINE FORMS OF 6-N-

**PYRIDIYLMETHYLAMINOINDOLOCARBAZOLE** 

**COMPOUNDS** 

Commissioner of Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

# EXPLANATION OF RELEVANCE OF NON-ENGLISH DOCUMENTS UNDER 37 C.F.R. 1.98(a)(3)(i)

Sir:

Applicants respectfully note that two (2) of the documents listed on the USPTO 1449 for submitted herewith is not in the English language and a copy of an English translations of that documents is not within the possession, custody or control of Applicants, and, to the Applicants knowledge, is not readily available. Below is a concise explanation of the relevance of those non-English documents:

The Japanese patent publication JP 6-128283 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the JP 6-128283 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The PCT patent publication WO96/04293 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the WO96/04293 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The instant invention discloses novel polymorphic forms of a several 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having substituted and unsubstituted pyridylalkylamine substituents on the amine of the fused carbazol dione ring.

#### **CERTIFICATE OF MAILING**

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

Date: August 1, 2006

Respectfully submitted,

David A. Muthard Reg. No. 35,297

Attorney for Applicant(s)

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Rahway, New Jersey 07065-0907

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Sub	estitute for form 1449A/PTO			Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE  COMPLETE IF KNOWN			
IJ	NOITAMATION	DIS	CLOSURE	Application Number	10/565,327		
//	TATEMENT BY			Filing Date	January 20, 2006		
	AUG 07 2006 g	AP	PLICANI	First Named Inventor	Hideaki Imamura		
1~	<i>I</i> -/		,	Group Art Unit	To be determined		
1/4	(use as many sheets	as n	ecessary)	Examiner Name	To be determined		
Sheet	1	of	2	Attorney Docket Number	BY0018YP		

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
		5,591,842		Kojiri, et al.	01/07/1997		
		5,668,271		Kojiri, et al.	09/16/1997		
		5,804,564		Kojiri, et al.	09/08/1998		
		5,922,860		Kojiri, et al.	07/13/1999		
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			FOREIGN PA	ATENT	T DOCUMENTS	
Examiner Initials*	NING I		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
		PCT	WO 96/04293 (Explanation Att.)		Banyu Pharmaceutical Co., Ltd.	11/16/1995
		EPO	EP 528030		Banyu Pharmaceutical Co., Ltd.	09/17/1997
		JPO	JP 10-245390(Eng. Trans. Att.)		Banyu Pharmaceutical Co., Ltd.	09/14/1998
		JРO	JP 6-128283 (Explanation Att.)		Banyu Pharmaceutical Co., Ltd.	05/10/1994

Examiner Signature	Date Considered	

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

Approved for use through 7/31/2006. OMB 0651-0031 SUBSTITUTE for PTO/SB/08A (07-05), Information Disclosure Statement by Applicant

Su	bstitute for form 1449B/PTO			Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE  COMPLETE IF KNOWN			
	NFORMATION	DIS	CLOSURE	Application Number	10/565,327		
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			,	Group Art Unit	To be determined		
	(use as many sheets as neceșsary)			Examiner Name	To be determined		
heet	2	of	2	Attorney Docket Number	BY0018YP		

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.					
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Examiner	Date	
Signature	Considered	
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<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form \* IDS Form\* (IDS Folder), Merck & Co., Inc., -7/12/2005)